Remarks

This Amendment is in response to the Office Action dated **May 18, 2005.** Claims 47-63 are pending in this application. The Office Action rejected claims 47-63 citing 35 USC § 103 over Wand et al. (US 5525388; hereinafter "Wand").

By this Amendment, claims 64-67 are added. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

Claim Rejections

The Office Action rejected, under 35 USC § 103, claims 47-63 over Wand. These rejections are traversed.

Applicants assert that Wand does not disclose or suggest a method including "providing a medical balloon," and "removing material from at least one portion of the proximal end and distal end portions of the balloon," as recited in independent claim 47 and similarly recited in independent claim 60. Wand only teaches removing material from a parison or balloon precursor.

Wand discloses a balloon 12 at Figure 4 and a parison 30 or tubular member at Figure 5. Wand states that the parison 30 can be used to form the balloon 12. See column 4, lines 7-8. Thus, the parison of Figure 5 is a precursor to a balloon and may be modified to produce the balloon of Figure 4. For example, the parison 30 may be blown into the balloon 12 by subjecting the parison 30 to elevated temperatures while inflating the parison 30 with inflation fluid at high pressures within a mold. See column 4, lines 16 – 23.

The Office Action alleges at page 3:

> Notice that removing material of a parison means removing the material of the balloon as well, because the parison and the balloon is essentially just one entity. It would have been obvious to one of ordinary skill in the art at the time of the invention to remove material of a parison/balloon so a to thin a portion of a parison/balloon to make the balloon to have a better profile for easy deployment in a patient body.

As previously asserted in the Amendment filed 3/4/05, Applicants assert that the parison disclosed in Wand is not a balloon, and thus, operations performed on the parison do not

render the method of claims 47 or 60 unpatentable. A person of ordinary skill in the art would understand that a parison is by definition a precursor to a balloon, and therefore not a balloon. Removing material from the parison prevents the removed material from ever becoming part of a balloon.

Wand specifically discloses a balloon at Figure 4 and a parison at Figure 5. The Office Action included a copy of each Figure at page 2, with markings to indicate which elements of the parison correspond to balloon elements after the parison has been molded into the balloon. The differing structural features between Figures 4 and 5 provide sufficient evidence to conclude that a balloon is not a parison. Further, a person of ordinary skill in the art would understand that the balloon of Figure 4 could be provided in a deflated configuration and inflated to expand a stent. A person of ordinary skill in the art would also recognize that the parison is not considered an inflatable device and would not be suitable for expanding a stent.

Wand specifically teaches making a parison of a desired size and shape which will then be molded to form a balloon with an essentially constant wall thickness. See column 2, lines 45-53; column 3, lines 14-22. Wand does not disclose or suggest removing material from a balloon that has already been formed, as described by Applicants at least at page 11, lines 18-20 of the application and recited in independent claims 47 and 60.

Applicants assert that for the purposes of the Wand invention, the parison and the balloon cannot be considered equivalent. A person of ordinary skill in the art would recognize that the parison is easier to machine than the balloon because the greater thickness of the parison imparts greater structural integrity. Further, the subsequent balloon forming step allows for mold-smoothing of any surface irregularities introduced during machining of the parison. For at least the reasons that balloons are thinner and that mold-smoothing does not occur after balloon formation, a person of ordinary skill in the art would not consider it obvious to remove material from the balloon rather than the parison as taught by Wand.

The Examiner has provided no prior art motivation to modify the teachings of Wand to first mold the balloon and then perform operations on the balloon to arrive at the desired balloon size and shape. Absent any such prior art motivation, Applicants assert that independent claims 47 and 60 are patentable over Wand. Claims 48-59, which depend from independent claim 47, and claims 61-63, which depend from independent claim 60, are patentable over Wand

for at least the reasons discussed with respect to independent claims 47 and 60.

Further, with respect to claims 47-59 and 61-62, the Office Action recites at page 3:

> WAND does not explicitly disclose maintaining the temperature of the balloon below glass transition temperature or below highest glass transition temperature for the balloon's thermoplastic material. However, cooling a material at a cutting site with a coolant such as water/fluid/gas/air/oil is a well known process in machining the material with a machine tool such as a grinder/a lathe/a drill machine so as to maintain the cutting site at low temperature for an effective and accurate cutting and inherently, the temperature must be maintained below a glass transition temperature or below a highest glass transition temperature for a thermoplastic material to avoid deformation or sticking of the material at the cutting site.

Without forming an opinion as to the validity of the Examiner's assertions, Applicants request that any facts or teachings not disclosed in the applied prior art references, and thus contained within the personal knowledge of the Examiner, be supported by an affidavit as provided for in 37 CFR § 1.104(d)(2).

Further, Applicants assert that a cutting site may be provided with water/fluid/gas/air/oil for many reasons, such as for lubrication, to protect tooling, prevent warping, and to carry away removed material. Therefore, a general teaching of using water/fluid/gas/air/oil during machining does not comprise a specific teaching of cooling the material being machined to a level below the glass transition temperature of the material.

Additionally, Wand does not disclose or suggest the use of block copolymers. Therefore, no prior art reference has been applied which suggests the use of block copolymers for balloons. There is no prior art teaching that grinding or chemical etching are suitable methods for removing block copolymer material, for example as recited in claim 51, and there is absolutely no teaching of maintaining the temperature of a block copolymer below its highest glass transition temperature during material removal.

Accordingly, Applicants request the withdrawal of the rejections under 35 USC § 103.

New Claims

Claims 64-67 are added. Claim 64 specifies that the thermoplastic material comprises a block copolymer. The applied prior art fails to disclose or suggest block copolymers.

Claims 65 and 67 include the limitations of "providing a parison and stretching the parison to form the balloon." Support for the claims may be found at least at page 2, lines 9-11 and page 11, lines 16-20. These claims further support Applicants' assertion that a parison is not a balloon.

Claim 66 includes the limitations "wherein the step of removing material comprises removing material from an outer surface of the balloon." A person of ordinary skill in the art would understand that the grinding and etching methods disclosed may remove material from the outer surface of the balloon. For example, the centerless grinder shown in Figure 3 can remove material from an outer surface of a balloon.

Wand teaches removing material from an inner surface of a parison. Wand discloses forming a tubular member and then thinning the wall by "machining, abrading or other suitable means." The only indication of the location of the material being removed from the parison is contained in Figure 5, which shows a parison having a constant outer diameter and a varying inner diameter. Wand does not disclose or suggest removing material from an outer surface of the parison.

Conclusion

Based on at least the foregoing amendments and remarks, Applicants respectfully submit this application is in condition for allowance. Favorable consideration and prompt allowance of claims 47-67 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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